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by Katherine Abel, CPC,
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Joint Commission reports improved quality of care

Hospitals accredited by The Joint Commission have demonstrated continual improvement over the seven-year period from 2002 to 2008, according to its report, “Improving America’s Hospitals: The Joint Commission’s Annual Report on Quality and Safety 2009.”

Heart attack, heart failure, and pneumonia patients. Hospitals accredited by The Joint Commission improved the quality of care provided to heart attack patients, heart failure patients, and pneumonia patients. Hospitals are providing on a more consistent basis evidence-based treatments, which are practices shown by scientific evidence to lead to the best outcomes for patients, according to composite quality performance results for heart attack, heart failure, and pneumonia care compiled over the seven-year period.

Specifically, the 2008 heart attack result is 96.7 percent, an improvement of 9.8 percentage points from the 2002 result. (The 96.7 percent score means that hospitals provided an evidence-based heart attack treatment 967 times for every 1,000 opportunities to do so.) The 2008 heart failure care result is 91.6 percent, an improvement of 31.9 percentage points from the 2002 result. Finally, the 2008 pneumonia care result is 92.9 percent, an improvement of 20.6 percentage points from the 2002 result.

Surgical care performance. Hospitals have shown steady improvement on individual surgical care performance measures, as well as additional individual heart attack and pneumonia care measures, over a two-, three-, or four-year period. For example, the most significant improvements for individual measures for each quality measure include the following:

- For heart attack patients, smoking cessation advice improved 66.6 percent in 2002, and continued to improve each subsequent year, up to 98.9 percent in 2008.
- For heart failure patients, smoking cessation advice improved 42.2 percent in 2002, and continued to improve each subsequent year, up to 97.6 percent in 2008.
- For pneumonia patients, smoking cessation advice improved 37.2 percent in 2002, and continued to improve each consequent year, up to 96.0 percent in 2008.

Moreover, hospital performance on two individual quality measures relating to inpatient care for childhood asthma is excellent after one year of measurement: (1) a 99.8 percent performance level on providing relievers to childhood asthma inpatients, and (2) a 99.1 percent performance level on providing systematic corticosteroids to childhood asthma inpatients.

High performance, room for improvement. Ninety percent of the hospitals achieved greater than 90 percent performance on eight of the 28 measures tracked during 2008. The best performance was in measuring oxygen in blood for pneumonia patients: 99.7 percent of hospitals achieved rates over 90

percent in 2008. More than 95 percent of hospitals scored over 90 percent in 2008 on three other measures related to heart attack care. Performance on the other 24 measures ranged from 94.8 to 4.9 percent. Four of the 28 measures had performance levels of 50 percent or less.

Despite the fact that hospitals averaged 90 percent or better performance on most individual quality measures, The Joint Commission noted that more improvement is needed and cited two examples of relatively low performance on two measures in 2008: (1) a 52.4 percent performance level on providing

fibronolytic therapy within 30 minutes of arrival to heart attack patients, and (2) a 60.3 percent performance level on providing antibiotics to intensive care unit pneumonia patients within 24 hours of arrival. ■

The Joint Commission's Annual Report on Quality and Safety 2009, Jan. 2010

Antitrust

FTC, Congress call for end to generic drug "pay-for-delay" deals

Federal Trade Commission (FTC) Chairman Jon Leibowitz and certain members of Congress have renewed a call for legislation that would end "pay-for-delay" deals, in which brand-name drug manufacturers settle patent litigation with generic competitors by paying them to keep cheaper generic alternatives off the market. Chairman Leibowitz has urged Congress to adopt such a ban as part of any health care reform legislation, stating that "pay-for-delay deals are a bad prescription for America: when drug companies agree not to compete, consumers lose." Republican FTC Commissioner J. Thomas Rosch is in agreement, writing, "As I testified last year...almost all, if not all, reverse payment agreements...delay generic competition longer than it might otherwise occur."

Background. Under the patent exclusivity provisions of the Hatch-Waxman Act (PubLNo 98-417), a generic competitor may seek market entry prior to expiration of the patents on a brand-name drug. In fact, generic drug manufacturers have an incentive to challenge brand-name patents because the first generic to file its application with the Food and Drug Administration (FDA) can obtain 180 days of marketing exclusivity during which it is the only generic on the market. To obtain FDA approval for market entry of a generic version before patent expiration of the brand-name drug, a generic must declare that its product does not infringe the relevant patents of the brand-name manufacturer or that the relevant patents

are invalid. As a practical matter, brand-name manufacturers normally challenge the generic's declaration, and litigation ensues. For the brand to prevail and block entry, it must successfully defend the validity of its patents and demonstrate that the generic's product would infringe those patents.

2002 FTC study. A 2002 FTC study showed that generics prevailed in 73 percent of the patent litigation cases ultimately resolved by a court decision between 1992 and 2002. Given the costs and uncertainty of patent litigation, however, brand-name and generic drug manufacturers sometimes settle before a final court decision. For example, the parties may agree that the generic can enter the market at some point before the patent's expiration date, but not as quickly as the generic could obtain through litigation. If no compensation is paid to the generic for the delay in its market entry, these settlement agreements are unlikely to raise antitrust issues. The 2002 study determined, however, that some brand-name and generic manufacturers had settled their patent litigation through agreements that compensated generics for substantial delays in market entry. As a result, the FTC recommended and Congress subsequently required, under provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (PubLNo 108-173), that drug companies file their patent settlement agreements with the FTC within ten days of their execution.

New study. A new FTC study, entitled "Pay-for-Delay: How Drug Company

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Antitrust (cont.)

Pay-Offs Cost Consumers Billions,” summarized findings from patent settlement agreements filed with the FTC from fiscal year 2004 to 2009 pursuant to the MMA. The new study made the following findings as to these agreements:

- Sixty-six agreements involved some form of compensation from the brand to the generic combined with a delay in generic market entry.
- Out of 218 agreements filed, 70 percent did not involve compensation from the brand to the generic combined with a delay in generic entry.
- Agreements with compensation on average prohibit generic entry for nearly 17 months longer than agreements without payments.

- Out of 66 agreements that combined compensation from the brand to the generic with deferred generic entry, 77 percent were between the brand-name manufacturer and the generic that was the first to seek entry prior to patent expiration for the relevant brand-name drug. These agreements typically ensure the brand-name drug's lock on the market because every subsequent generic entrant has to wait until the first generic has been marketed for 180 days.
- Approximately 25 percent of patent settlement agreements with first-filer generics involved an explicit agreement by the brand not to launch an “authorized generic” (AG) to compete

against the first filer generic, combined with an agreement by the first-filer generic to defer market entry past the date of the agreement. While this does not involve an actual dollar payment to the generic, the brand is agreeing not to cut into the generic's profits with an AG.

The study concludes that most of the pay-for-delay agreements reached since 2005 are still in effect, currently protecting at least \$20 billion in sales of brand-name drugs from generic competition. The FTC study recommends that Congress pass legislation to protect consumers from these anti-competitive agreements. ■

FTC Staff Study, Jan. 2010

Trends

MedPAC votes on payment recommendations

At its January 14th-15th meeting, the Medicare Payment Advisory Commission (MedPAC) voted on a series of Medicare payment recommendations. These recommendations will be included in its March 2010 report to Congress. MedPAC recommends that Congress:

Hospitals. Increase payment rates for the acute inpatient and outpatient prospective payment systems in 2011 by the projected rate of increase in the hospital market basket index, concurrent with implementation of a quality incentive payment program; and, to restore budget neutrality, require the Secretary of HHS to fully offset increases in inpatient payments due to hospitals' documentation and coding improvements. To accomplish this, the Secretary must reduce payment rates in the inpatient prospective payment system by the same percentage (not to exceed 2.0 percentage points) each year in 2011, 2012, and 2013. The lower rates would remain in place until overpayments are fully recovered.

Physicians. Update physician payments for physician services in 2011 by 1.0 percent.

Ambulatory surgical centers.

Implement a 0.6 percent increase in the payment rates for ambulatory surgical center (ASC) services in calendar year 2011 concurrent with requiring ASCs to submit cost and quality data.

Dialysis. Update the composite rate by the projected rate of increase in the end-stage renal disease (ESRD) market basket index less the adjustment for productivity growth for calendar year 2011.

Skilled nursing facilities. Eliminate the update to payment rates for skilled nursing facility services for fiscal year 2011.

Home health. Eliminate the market basket update for 2011, and direct the Secretary to: (1) rebase rates for home health care services to reflect the average cost of providing care; (2) expeditiously modify the home health payment system to

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The Road to ICD-10 Compliance

by Katherine Abel, CPC, CPC-I, CMRS

Although physicians, coders and staff do not need to learn the ICD-10-CM code set for another couple years, every medical practice and facility, small to large, should begin preparing now for a smooth implementation transition. In this article, we will review 16 steps for a successful ICD-10 implementation.

On January 16, 2009, the Department of Health and Human Services announced that HIPAA Administration Simplification will modify the medical data codes set standards to adopt ICD-10-CM (International Classification of Diseases, 10th Revision, Clinical Modification) and ICD-10-PCS (International Classification of Diseases, 10th Revision, Procedure Coding System). The effective date for compliance is October 1, 2013. ICD-10-CM and ICD-10 PCS will replace the current ICD-9-CM coding system with ICD-10-CM replacing Volumes 1 and 2 and ICD-9-PCS replacing Volume 3. Preceding implementation for ICD-10 is the compliance date for the new 5010 version of the transaction standard x12—January 1, 2012 for most health care entities; January 1, 2013 for small health plans.

Currently, ICD-9-CM is used to calculate MS-DRGs (Medicare Severity—Diagnosis Related Groups), as diagnoses to support medical necessity in all settings, statistical reporting, and quality analysis and ICD-9-PCS is used to report inpatient procedures in a hospital setting. The move to the ICD-10 data set will modernize terminology, increase information for public health surveillance and quality reporting, and allow flexibility for expansion to accommodate rapid incorporation of emerging technology into the code set. Diagnoses and procedure codes impact virtually every system and business process in plan and provider organizations, with significant impacts on billing and reimbursement, which is why physician offices, hospitals, and other health care settings need to start preparing now.

Here is the 16 step road to ICD-10 compliance:

Step 1: Organize the Implementation Effort

Successful implementation of ICD-10 will begin with identifying a point person to take responsibility for the implementation process. The point person will be responsible for addressing key issues and formulating the plan for implementation. To help with the implementation process, a steering committee involving a key player in each department of the organization should be developed, including senior managers, physicians, compliance officers, coders, and IT personnel.

Initial steps should include performing an initial impact analysis covering all areas of the organization, including the clinical team, the IT department, and all business operations.

Once the areas of impact are identified, the committee will need to determine the sequencing of activities along with other related projects such as the 5010 implementation and EHR implementation if applicable.

Step 2: Develop a Communication Plan

How often have we heard communication is key? During the planning phase, the steering committee will need to determine the avenue and frequency of communication during the ICD-10 implementation process. The steering committee should conduct periodic briefings for staff or include information in other communication formats (i.e. newsletters, e-mails, etc.). A solid plan for communication should include monthly meetings with the staff until six months prior to implementation, at which time communication efforts should be increased to bi-weekly. Sharing information such as articles, publications, and briefings will help your staff stay informed and be prepared when implementation time arrives.

Although contacting your system vendors is covered in Step 8, you will want to begin your calls to the vendors during Step 2. You will need to get your system vendors working on the implementation process if they have not already begun. Vendor responses will affect your budgeting and timeline for the implementation process. Question your vendors on their ability to accommodate the move to ICD-10 prior to the compliance date, and if they will be ready for version 5010 prior to January 1, 2012. Have them share their coordination and implementation plans for both 5010 and ICD-10 implementation. Verify if the conversions and upgrades are included in your contract, or if there will be additional fees associated with the upgrades.

Thorough planning now will assist your practice or facility in an efficient and smooth transition.

Step 3: Conduct an Impact Analysis

Conducting an in-depth impact analysis on your practice will assist in determining the timing requirements as well as budgetary concerns. This includes a high level review of regulatory requirements, timelines, and resources needed over the next several years and identifying a source of funding and coordinator of the project.

To perform an impact analysis, you will want to review all areas of your practice that will be impacted by the implementation of ICD-10. This includes your practice management system, any electronic coding systems, electronic medical records, and the hardware required to house the systems currently running. Remember, you will now be hosting two data sets, ICD-9-CM concurrently with ICD-10-CM and ICD-10-PCS, if applicable. Identify the general impact of the coding changes, changes to be made to your current reports and trending efforts, new processes needed as a result of ICD-10, and additional quality efforts needed to ensure proper coding specificity. This is also an excellent opportunity to review existing operations within the practice and consider areas of improvement—not just meeting the compliance data but developing better operations, performance, quality, etc. A thorough, in-depth impact analysis should take approximately six months to complete.

Step 4: Organize Cross-Functional Efforts

Medium to large practices and facilities will need to organize and coordinate cross-functional efforts. Identify staff to represent cross-functional areas and establish lines of communication. For cross-functional areas to implement ICD-10 effectively, establish meeting schedules and reports, including the frequency of briefing senior management on progress or problems. To avoid friction, be clear on who has decision-making authority within the teams. A gap analysis will help the teams of the different areas determine where they need to work to close the gaps.

Step 5: Budget Development

Creating a budget for ICD-10 implementation may be a moving target. Because of this, make sure you reassess your budget at least every six months. Your budget should include all costs associated with ICD-10 implementation, including staff training time (including overtime and temporary help), software and hardware costs, workflow process changes, and testing. When reviewing the software and hardware costs, keep in mind your software licenses and upgrade fees associated with them. Keep in constant communication with your vendors so you can plan your budget accordingly. While creating your budget, keep in mind there may be a reduction in financial income from insurance companies as they make the switch. Have a rainy day fund set aside to cover your organization during the transition time.

Step 6: Internal System Design and Development

Medium to large organizations may have their own internal systems requiring reprogramming. If your practice has its own proprietary systems, you will need to prepare for the design,

programming, and testing of the internal systems. The IT staff will also need to map the ICD-9 to ICD-10 and ICD-10 back to ICD-9, or they can use the mapping available on the CMS website. Make sure your IT department is aware of the 5010 version requirements and has a plan for updating the proprietary systems in your office.

Step 7: Development of the Training Plan

A training plan will be an essential tool for your office to ensure all staff receives the appropriate training for ICD-10. Coordinate your plan to occur in two phases. Phase I training should be a general overview of ICD-10, guidelines format and structure and Phase II training should be in-depth based on specialty. Identify which phase(s) each area of your staff will need to be involved in, starting with senior management. Cross-functional teams, clinical staff, coding and billing staff, financial staff, administrative staff, and providers will all need to be trained. Staff training should be based on their role within the practices.

Training can be conducted using internal resources, external resources, or a combination of internal and external resources. Evaluate your options to decide which resources are more beneficial for your practice. After determining your resources, develop a schedule for training and assess whether temporary help will be needed during the training phase. Communicate with the staff continually on the status of the training efforts.

Step 8: Contact System Vendors

You should already be in constant communication with your vendors by this point. If you have not contacted your vendors before now, you will need to contact them to assess their readiness for the ICD-10 implementation. Determine if your vendors are going to support the upgrade to ICD-10 and if they are going to have the capability to hold two date sets effectively (ICD-9 concurrently with ICD-10). Keep in mind that the upgrade of one system can affect multiple systems. Likewise, the upgrade of one piece of hardware can affect multiple pieces of hardware. Clarify the vendors' timeline for testing and implementation and modify your plans accordingly.

Step 9: Implementation Planning

This is the planning for how the project will be implemented by the organization. Break down the implementation into stages and identify who implements what and when each piece is implemented. As you develop your implementation plan, remember that Australia coders and doctors required 60 to 80 hours of training time on the new code set when they moved to ICD-10.

Determine the benefits to implementation and how to achieve those benefits. For example, review opportunities that could impact reimbursement, value-based purchasing, and pay-

for-performance. Take this opportunity to fine tune or change your current procedures. Map out your implementation plan, which can be completed in a simple excel file, or in a project planning software. Develop a communication plan with your staff and monitor training to ensure it is occurring during the appropriate times, and reevaluate the plan as necessary. This is also a good time to develop a post-implementation problem resolution process that will address how to report, track, prioritize, and correct issues identified. The implementation plan should be approved by the steering committee to have buy-in from the necessary team players.

Step 10: Phase I Training

Phase I training is a general training including ICD-10 Guidelines, understanding of the general code set, and the regulatory issues and guidance surrounding the use of ICD-10. You will want to reinforce the need for specificity and that documentation is key. All staff members should be involved in Phase I training which should take six to eight hours per individual and should occur about one year prior to the compliance date. Utilize some of the resources available at the American Academy of Professional Coders (AAPC), such as the free webinar series or audio conferences available for purchase. Providing training in one day, in most cases, is not retained for a long period of time for persons who will be using ICD-10-CM on a day-to-day basis.

Step 11: Business Process Analysis

Conduct an assessment of the impact of ICD-10 on all of your business processes. For example, you will want to conduct a review of your communications between departments (lab orders, radiology orders, etc.). Analyze your practice management, billing systems, registration processes, and contracts with health plans. During this step is the time to perform a baseline ICD-10 readiness audit. Why is performing an audit so important? In order to move readiness going forward, it is important to identify current areas for improvement in documentation when reporting diagnoses in the medical record. Look at each business process that currently addresses or uses ICD-9 and evaluate the impact of ICD-10 on that process. Be sure to include your payer contracts in this analysis.

Step 12: Education and Training—Phase II

This training should include ICD-10 code set training based on your specialty. By comparing applicable guidelines and codes, you should have a clear understanding when finished. This is also a good time to crosswalk and map ICD-9 codes you use routinely in your organization to the ICD-10 code set, and update superbills if you use them. This is detailed training on using the ICD-10 code set. Remember, your certified coders will also need to pass a proficiency exam in ICD-10 coding in order to maintain their certification.

Step 13: Policy Change Development

As you near the implementation date, you will want to identify opportunities to improve processes. Make changes to policies identified in your gap analysis and educate the providers and staff on the policy changes. You will want to wait to begin this process after carriers begin changing payment policies.

Step 14: Outcomes Measurement

One to three months prior to implementation, it is a good idea to measure the coders' and providers' understanding of ICD-10-CM and provide customized learning to fill any knowledge deficits. New policies and procedures as part of the practice compliance plan should be formulated at this time.

Step 15: Deployment of Code by Vendors to Customers

Work with system vendors regarding upgrades from ICD-9 to ICD-10 beginning at least one year prior to ICD-10 "Go Live." However, begin talking to system vendors two years prior to implementation. Multiple code sets including ICD-9-CM, ICD-10-CM, ICD-10-PCS, CPT and HCPCS must all be supported in the system upgrade. Changing code sets will involve more than expansion of the field definition to seven characters in the databases where the procedure codes and diagnosis codes are stored, although that will be part of the process. Since the size of ICD-10-CM/PCS is much larger than ICD-9-CM, fields will need to be modified within the system to accommodate the alphanumeric codes. Both the new and old codes will need to be supported since they will run simultaneously. Keep in mind many health care payers and third party payers will not convert all at one time. Also consider old claims prior to the "go live" date will need to be stored.

Step 16: Go Live—Implementation Compliance

Measure coder productivity and perform internal testing of your coding and billing staff. Provide additional education and training if deficiencies are identified. After implementation, perform another outcomes measurement to ensure you are in compliance with the ICD-10 code sets.

By planning ahead, utilizing the talent and resources in your medical practice, and keeping up on legislative progress on ICD-10-CM/PCS, the practice will afford a fairly smooth transition. Be sure to visit <http://www.aapc.com/> to utilize the planning tracker and other ICD-10-CM implementation tools available to AAPC members.

Katherine Abel, CPC, CPC-I, CMRS, is director of curriculum at the American Academy of Professional Coders.

Inappropriate marketing of MA plans

In response to complaints that some Medicare Advantage (MA) organizations and their agents have inappropriately marketed their health plans to Medicare beneficiaries, members of Congress and state agencies asked the Government Accountability Office (GAO) to examine (1) the extent of compliance and enforcement actions by the Centers for Medicare & Medicaid Services (CMS), (2) how CMS has helped beneficiaries affected by inappropriate marketing and the problems beneficiaries have encountered, and (3) information CMS has about the extent of inappropriate marketing.

CMS compliance and enforcement actions. According to the GAO, from January 2006 through February 2009, CMS took compliance and enforcement actions for inappropriate marketing against at least 73 out of approximately 192 organizations that sponsored MA plans. CMS actions ranged from initial notices of noncompliance and warning letters to civil money penalties and suspensions of marketing and enrollment.

Help provided to beneficiaries. Beneficiaries who experienced inappropriate marketing have been assisted by special election periods (SEP) through which they could disenroll from their MA plan and enroll in new coverage without waiting for the twice yearly regular enrollment periods. The SEPs, however, did not address certain financial or access-to-care problems beneficiaries experienced as a result of inappropriate marketing. For example, when beneficiaries disenrolled from their MA plans and Social Security did not stop the withholding of their premiums promptly, financial hardship resulted. In addition, because of inappropriate marketing practices, some beneficiaries did not realize they had been enrolled in an MA plan until they tried to access services. These beneficiaries experienced disruption of their access to providers and medications when they discovered their providers did not participate in their new MA plan.

Extent of inappropriate marketing. The GAO is concerned that some ben-

eficiaries may have disenrolled from their MA plans during regular enrollment periods and might not have notified CMS of the marketing problems they encountered. The GAO reports that approximately 21 percent of beneficiaries disenrolled in 2007 from one type of MA plan that had a high incidence of inappropriate marketing. The actual figures are uncertain, however, because CMS discontinued a survey on disenrollment reasons after 2005 that could have provided information about the extent to which the disenrollments were the result of inappropriate marketing. CMS plans to reinstitute a survey on disenrollment reasons in 2010. CMS also has limited information about the number of beneficiaries who disenrolled for inappropriate marketing because it failed to track the number of SEP disenrollments,

Recommendations. The GAO recommends that CMS gather more information on the extent of inappropriate marketing and CMS concurred with the recommendation. ■

GAO Report, GAO-10-36, Dec. 17, 2009

OIG Special Fraud Alert: DME suppliers' telemarketing

The Office of Inspector General (OIG) updated its Special Fraud Alert that ad-

ressed telemarketing by durable medical equipment (DME) suppliers. The original Special Fraud Alert, reported in March 2003, highlighted the statutory provision in 42 U.S.C. §1395m(a)(17)(B) that prohibits DME suppliers from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a covered item.

There are three exceptions to this prohibition: (1) the beneficiary gave written permission; (2) the contact regards a covered item already furnished; and (3) the supplier had furnished at least one covered item during the preceding 15 months. In addition, 42 U.S.C. §1395m(a)(17)(B) prohibits payment to a supplier that knowingly submits a claim generated pursuant to a prohibited telephone solicitation.

The OIG has received credible information that some DME suppliers continue to use marketing firms to make unsolicited telephone calls in violation of the statutory prohibition. Some DME suppliers are contacting Medicare beneficiaries by telephone based solely on a treating physician's preliminary written or verbal orders prescribing DME for beneficiaries. A physician's preliminary written or verbal order is not a substitute for the requisite written consent of a Medicare beneficiary. ■

Notice, 75 FR 2105, Jan. 14, 2010, Health Care Compliance Reporter, ¶520,030

Trends (cont.)

protect beneficiaries from stinting or lower quality of care in response to rebasing (the approaches considered should include risk corridors and blended payments that mix prospective payment with elements of cost-based reimbursement); (3) identify categories of patients who are likely to receive the greatest clinical benefit from home health and develop outcomes measures which measure the quality of care for each category of patient; and (4) review home health agencies that exhibit unusual patterns of claims for payment (providing that the Secretary has the authority to implement safeguards, such as a moratorium on new providers, preauthorization, or suspension

of prompt payment requirements, in areas that appear to be high risk).

Inpatient rehabilitation facilities. Eliminate the update to the payment rates for inpatient rehabilitation services for fiscal year 2011.

Long-term care hospitals. Direct the Secretary to eliminate the update to payment rates for long-term care hospitals for rate year 2011.

Hospice. Update the payment rates for hospice for 2011 by the projected rate of increase in the hospital market basket index less MedPAC's adjustment for productivity growth. ■

MedPAC Recommendations, Jan. 2010

Sen. Grassley conducts HIT surveys, introduces fraud bill

Senator Charles Grassley (R-Iowa) has sent letters to 31 hospitals nationwide asking about their experiences in implementing the \$19 billion federal health information technology (HIT) program. Sen. Grassley's hospital survey is based on concerns of administrative complications, formatting and usability issues, errors and interoperability of HIT software. Specific provider concerns expressed to Grassley include the following: (1) HIT software has produced incorrect medication dosages due to miscalculated body weights caused by interchanging kilograms and pounds; (2) difficulties encountered in approaching the HIT vendor with problems and the lack of venue to discuss these issues; (3) alleged "gag orders" or non-disclosure clauses in HIT contracts that prohibit providers from sharing information regarding product defects and other HIT concerns; (4) for HIT products that do not fall under the Food and Drug Administration's device regulations, there appears to be a lack of a national system for reporting product failures and adverse events associated with the use of HIT products; and (5) contractual restrictions on the sharing of experiences and information related to specific vendor products may also limit a facility's ability to make informed decisions about HIT adoption and implementation.

Grassley has also introduced the "Strengthening Program Integrity and Accountability in Health Care Act," a bill to fight fraud, waste and abuse in Medicare, Medicaid and the Children's Health Insurance Program. Among other things, the bill aims to deter fraud with enhanced screening to improve the government's ability to keep fraudulent providers from participating in these programs from the start, and limit tax dollars lost to fraud by giving the government more time than is allowed under the existing pay-and-chase model to evaluate the legitimacy of Medicare providers before payment is required when fraud, waste and abuse are suspected. ■

Sen. Grassley Press Releases, Jan. 20 and 28, 2010

In the News

Colorado medical device agrees to pay \$5 million

Spectranetics Corporation, a Colorado-based manufacturer of medical lasers and peripheral devices, has agreed to pay \$4.9 million in civil damages plus a \$100,000 forfeiture to resolve claims that the manufacturer illegally imported unapproved medical devices, provided them to physicians for use in patients, conducted a clinical study in a manner that failed to comply with federal regulations, and promoted certain products for procedures for which the company had not received Food and Drug Administration approval. Spectranetics has entered into a civil settlement agreement, a non-prosecution agreement, and a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. Under the civil settlement agreement, the United States asserted that Spectranetics caused false claims to be submitted to the Medicare Program during portions of the time period from 2003 to 2008. Spectranetics has accepted responsibility for its conduct, instituted remedial measures to prevent this conduct in the future, and will continue to cooperate in the ongoing criminal investigation.

DOJ News Release, Dec. 29, 2009

Michigan provider settles false claims allegations

Genesys Health System, a Grand Blanc, Michigan-based provider of health care services through a network of medical facilities, has agreed to pay \$669,413 to settle a lawsuit alleging it violated the False Claims Act by submitting false claims to Medicare. The Department of Justice alleged that between 2001 and 2007, Genesys billed Medicare for higher levels of service for evaluation and management of cardiology patients than were actually rendered to the patients. The allegations were initiated by a lawsuit filed under the *qui tam* or whistleblower provisions of the Act. The whistleblower will receive a \$133,882 share of the settlement.

DOJ Press Release, Dec. 28, 2009

Summit on health care fraud held

HHS Secretary, Kathleen Sebelius, and Attorney General (AG), Eric Holder, convened with private sector leaders, law enforcement personnel, and health care experts at the National Summit on Health Care Fraud. The National Summit is the first national gathering on health care fraud between law enforcement and the private and public sectors, and is part of the Obama Administration's coordinated effort to fight health care fraud. The National Summit featured discussion on the elimination of fraud and abuse in the health care system and conducted workshops focusing on, among other things, the use of technology to prevent and detect fraud and improper payments, the role of states in preventing fraud, and the development of effective prevention policies and methods for insurers, providers and beneficiaries. "Health care fraud isn't just a government problem. Criminals don't discriminate and they are stealing from Medicare, Medicaid and private companies at an unacceptable rate," said Sebelius. "We have a shared interest in stopping these crimes and today's summit brought us together to discuss how we can all work together to fight fraud."

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